

## **PSJ2 Exh 4**

Counseling Your Patients  
and Their Families  
Regarding The Use of Opioids  
to Relieve Pain



A Service of Purdue Pharma L.P. and  
The Purdue Frederick Company, makers  
of analgesic products for pain control.

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*"What cannot be cured,  
must be endured."*

This old adage reveals a disturbing mindset shared by many patients with chronic pain.

Certainly, no one *wants* to be in constant pain. But many will endure it...for fear of something worse.

What is it they fear? Why are so many patients reluctant to report pain and/or take analgesics?\*

Research suggests that patients fail to report pain for several reasons<sup>1</sup>:

- Being thought of as a "weakling," "complainer," or "bad" patient
- Not wanting to distract the physician's attention away from the primary disease
- Unwillingness to acknowledge worsening disease (which they think pain signals)
- Fear of the drugs used to treat pain

To this last point a 1994 Harris poll found that—among patients who had been treated for pain 6 months or longer—more than 60% expressed hesitation to take even the most common prescription and nonprescription pain medications (such as ibuprofen, acetaminophen, and codeine combinations).<sup>2</sup>

\*A recent survey asked 897 physicians to rank potential barriers to effective pain management. Patient reluctance to report pain and take opioids were among the top three mentioned.<sup>3</sup>

If so many patients feel this way about relatively less strong analgesics, one can only imagine the resistance to the opioid analgesics—a particularly distressing situation since no other class of analgesics provides such dramatic pain relief.

Virtually every authoritative body—from The World Health Organization (WHO) to the Agency for Health Care Policy and Research (AHCPR)—agrees that opioids are central to the treatment of moderate to severe pain.<sup>4</sup>

In cancer patients, “Opioids are the major class of analgesics used in the management of moderate to severe pain because of their effectiveness, ease of titration, and favorable risk-to-benefit ratio,” according to the AHCPR.<sup>4</sup>

Opioids have their place in noncancer pain as well. As the eminent pain expert, Russell K. Portenoy, MD, recently remarked “[P]ain specialists now consider opioid therapy appropriate, safe, and effective on a long-term basis for selected patients with chronic nonmalignant pain, provided that patients are carefully monitored. [T]he risk of opioid abuse or addiction in patients without prior histories of abuse is extremely rare.”<sup>5</sup>

With the potential for significant improvements in pain management, it is important for healthcare providers to allay any fears patients may have about taking opioids. Failure to do so will likely result in nonuse or improper use. (It is estimated that between 13% and 57% of patients misunderstand or are noncompliant with prescribed pain treatments.<sup>3</sup>)

When a patient's fears and anxieties are anticipated and addressed before opioid therapy is begun, a successful outcome is much more likely.

Numerous surveys have identified the concerns uppermost in patients' minds. The following pages address those concerns and suggest appropriate replies.

Q

**Question...**

Isn't pain an unavoidable  
consequence of my illness?  
Shouldn't you  
be concentrating instead on the  
treatment of my disease?



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A

***You might reply...***

•Pain might be a consequence of your disease, but it's not unavoidable. Don't think you have to grin and bear it in order to be a "good" patient. Today, we can control your pain through relatively simple means, e.g., oral opioid medications.

•Better yet, we can prevent pain from occurring, rather than treating it when or after it occurs. Regularly scheduled, around-the-clock (not "as-needed") intake of opioids help to accomplish this purpose.

•Pain-free patients are a help, not a hindrance, to the treatment of the primary disease. With pain under effective control, patients enjoy a better quality of life. They can eat, sleep, perform daily activities more normally.

• Patients who are strong and rested are better able, both physically and mentally, to fight disease and actively participate in treatment.

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Q

**Question...**

Why are you prescribing  
such a strong drug for me?  
Is my condition  
getting worse?



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A

***You might reply...***

•Don't think "strong." Think "effective." The medicine I've prescribed—an opioid—is the most effective medication we have for your type of pain. Unlike nonopioid pain relievers, an opioid has no "maximum" daily dose—which allows us to adjust the dose to an effective level, no matter how severe your pain.

•Increasing pain does not necessarily mean worsening disease. Pain can sometimes be caused by the various treatments for the disease; sometimes by factors completely unrelated to the disease.

•Whatever the cause, keep in mind that effective control of pain improves a patient's ability to fight disease.

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Q

**Question...**

If I develop  
tolerance to this drug,  
what's left for me to take  
when I really need  
pain relief?



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A

***You might reply...***

•Tolerance to opioids may occasionally occur. Usually all it takes to correct this situation is to increase the dose. Remember, opioids are not limited to a "maximum" dose as nonopioids are—an effective dose can be found for virtually any type or severity of pain.

•Pain that "breaks through" near the end of a dosing cycle should be reported to the healthcare provider so that he or she can adjust the dose of the around-the-clock opioid.

•For pain that "breaks through" during periods of stress or increased activity, fast-acting opioids are available that supplement the action of the around-the-clock opioid. Taken an hour or so before the anticipated event, these fast-acting opioids can prevent even this type of pain from occurring.

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Q

**Question...**

Won't I  
(or my family member)  
become addicted to opioids  
and lose control?



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A

**You might reply...**

•Pain experts have recently redefined addiction as "the compulsive use of a drug for nonmedical purposes, usually with harm to the individual."<sup>2</sup>

•None of my patients fit this definition. Their use is not "compulsive," but stable and regularly scheduled. The medical purpose is clear...and the effects definitely beneficial, not harmful.

\* In fact, a survey of more than 11,000 opioid-using patients, taken over several years, found only four cases of documented addiction.<sup>6</sup>

*(To illustrate just how rare addiction is among pain patients taking opioids, administer the visual quiz on the next two pages. Many patients—and family members—will be surprised to discover that fewer than 1% of opioid-using patients become addicted!')*

Q

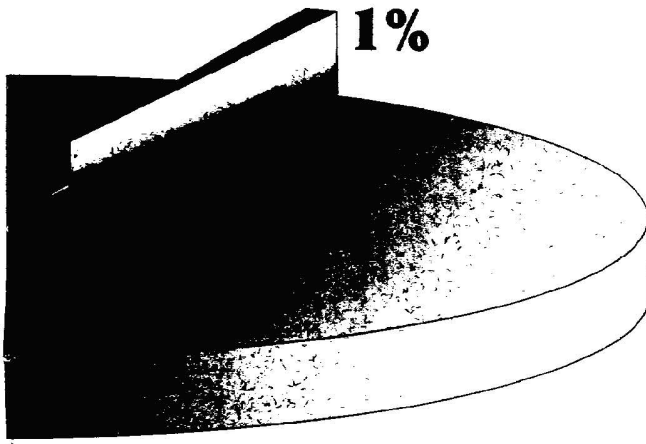
Among patients who regularly take  
opioids for pain, and have no history of  
substance abuse...

**Which percentage  
represents the proportion who  
become addicted?**



**99%**

A



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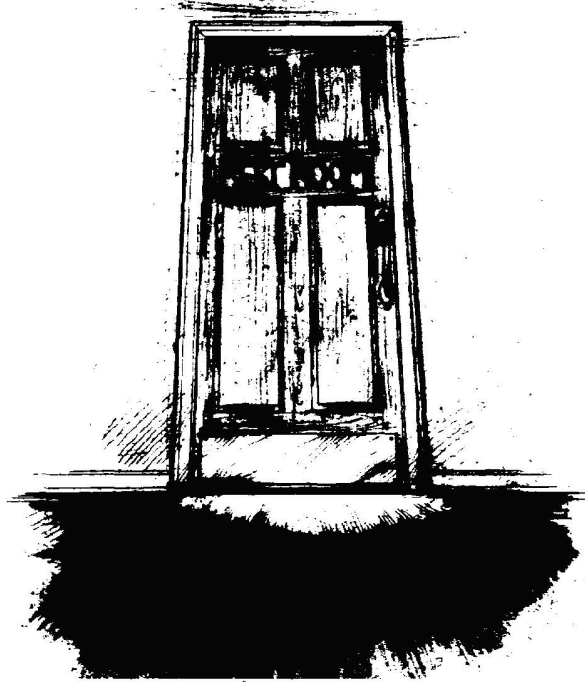
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Q

**Question...**

I've heard that opioid  
side effects are very unpleasant.  
Shouldn't I take as little  
of the opioid as possible...  
as seldom as possible?



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A

***You might reply...***

•Constipation is to be expected and can be treated preventively—with a stimulating laxative (such as Senokot-S®) with or without a stool softener.

•Most other opioid side effects diminish very quickly. Transitory sedation and/or confusion may occur during the first 24 to 48 hours after the initiation of opioid therapy or after a significant dose increase. Sedation and/or confusion usually lessen within 2 to 3 days after a stable dose has been established.<sup>7</sup>

•Nausea usually lessens within 3 to 4 days after beginning opioid therapy.<sup>8</sup> (Nausea may be the result of opioid-induced constipation. Alleviating constipation often alleviates nausea.<sup>9</sup>)

•All side effects are treatable and should be reported promptly. Remember that our goal—pain prevention—will be defeated if side effects cause a patient to discontinue, underdose, or take opioids on an “as needed” basis.

*While there are other barriers to effective pain management with opioids (poor pain assessment, for one), unfounded fears and apprehensions certainly play a major role.*

*The healthcare provider is key to resolving this situation. Conscientious and continual education of patients as to the nature of analgesic therapies, and their actual risks and benefits, will not only enhance patient compliance, but also contribute to long-term, around-the-clock pain control and a better quality of life overall.*



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makers of analgesic products for pain control.

Visit our Web site to learn more about pain management and prevention:  
[www.partnersagainstpain.com](http://www.partnersagainstpain.com)

**References:** 1. Mack JE. Management concepts in the treatment of cancer pain. *Hospital Pharmacist Report*. February 1995;24:33. 2. Rosendahl I. Painful truth. *Drug Topics*. November 21, 1994;39. 3. Von Roenn JH, Cleeland CS, Gonin R, et al. Physician attitudes and practice in cancer pain management. *Ann Intern Med*. 1993;119:121-126. 4. Jacox A, Carr DB, Payne R, et al. *Management of Cancer Pain. Clinical Practice Guideline No. 9. AHCPR Publication No. 94-0592. Rockville, Md.: Agency for Health Care Policy and Research, U.S. Department of Health and Human Services, Public Health Service, March 1994.* 5. Pain specialist calls for physician-regulator dialogue on opioid therapy. As reported in *PR Newswire*, November 17, 1996. 6. Porter J, Hick H. Addiction rare in patients treated with narcotics. *N Engl J Med*. 1980;302:123. 7. Levy MH. Pain management in advanced cancer. *Seminars in Oncology*. 1985;12:394-410. 8. Coluzzi PH. A model for pain management in terminal illness and cancer care. *Journal of Care Management*. 1996;2:45-76. 9. Levy MH. Constipation and diarrhea in cancer patients. *Cancer Bull*. 1992;43:412-422.

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